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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,959	02/25/2004	William Toreki	QMT1.1-CIP2-US	4101
3775	7590	08/13/2008	EXAMINER	
ELMAN TECHNOLOGY LAW, P.C.			ROGERS, JAMES WILLIAM	
P. O. BOX 209			ART UNIT	PAPER NUMBER
SWARTHMORE, PA 19081			1618	
			MAIL DATE	DELIVERY MODE
			08/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/786,959	Applicant(s) TOREKI ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60,61,64-68 and 70-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-61,64-68 and 70-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments to the claims filed 06/03/2008 have been entered.

Response to Arguments

Applicant's arguments, see Applicant Arguments/Remarks Made in an Amendment, filed 06/03/2008, with respect to the 35 U.S.C. 102(b) rejections over Marlin and Schoenfeldt have been fully considered and are persuasive. Marlin does not reasonably read on a material containing a substrate comprising a cationic polymer since the reference is drawn to aqueous solutions comprising cationic polymers used in drop type formulations (eye drops). Since the dressing materials of Schoenfeldt comprised essentially only the polymers and medicament the reference can no longer anticipate a material containing a substrate which comprises a cationic polymer. The 35 U.S.C. 102(b) rejections over Marlin and Schoenfeldt have been withdrawn.

Claim 61 is rejected under 35 U.S.C. 102(b) as being anticipated by Ward et al. (US 5,575,993), for the reasons set forth in the previous office action filed 03/06/2008.

Applicant's arguments filed 06/03/2008 have been fully considered but they are not persuasive. Applicants assert that Ward discloses solutions of poly-quaternary containing compositions which are added to bandages and gauzes and the solution can be washed off after normal wearing procedures and the polymers can adhere directly to surfaces for controlled delivery. Thus applicants surmise Ward can not read on their claims which require **binding** the polyquaternary to a substrate which Ward is silent upon.

Applicants lastly assert that Ward exemplifies that the polymer solution is used as is after its preparation.

The examiner respectfully disagrees with the above assertions by applicants. Firstly applicants do not claim that the polyionic polymer is covalently bound to the substrate surface, bound could have several meanings as to the type of bonding occurs, for instance weak bonding interactions such as van der Waals forces which includes hydrogen bonding, London forces, dipole-dipole forces reads on binding. Physical bonding or entrapment may also be encompassed within the term "bound". Thus simply because the poly-quat compositions of Ward are washable off of a bandage or gauze does not mean that there is an absence of weak intermolecular forces that can be considered as binding forces between the polyquat and the cellulosic material that comprises the bandage pad or gauze. Applicants claims as currently amended simply do not exclude weak intermolecular interactions. Regarding applicants assertion that the examples only show the use of a polymer solution, the examples within Ward were given solely for the purpose of illustration and were not to be construed as being limiting to their invention since many variations are possible without departing from the spirit and scope of the invention. Clearly Ward teaches that the polymer compositions can be applied to a bandage and gauze.

Claims 61 and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batich et al. (US 2002/0177828) in view of Ward et al. (US 5,575,993), for the reasons set forth in the previous office action filed 03/06/2008.

Applicant's arguments filed 06/03/2008 have been fully considered but they are not persuasive. Applicants assert as previously argued that Batich does not teach an anionic antibiotic active ingredient which is ionically associated with a quaternary ammonium polymer. Applicants further assert that one of ordinary skill in the art would not look to Ward as a source for the concept of extended release anions since the reference does not suggest this activity. As above applicants assert Ward does not teach that the ionene polymers could be bound to a woven article and instead are readily washed off the gauze.

The examiner respectfully disagrees with the above assertions by applicants. The examiner noted in the last office action that Batich does not disclose ionic association of the actives with the ammonium polymer, which is why it was combined with the Ward reference. If Batich did disclose anionic antibiotic, analgesic or anti-inflammatory the reference would be an anticipatory reference on its own merit, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As detailed in the previous office action Ward was used as a secondary reference for its disclosure that it was already known in the art that anionic antimicrobial compounds could be associated to cationic polymers. Since it would have been obvious to one of ordinary skill in the art that Batich and Ward are combinable, applicants claimed method of treatment comprising applying a cationic polymer with an ionically associated antimicrobial is obvious. As detailed above applicants assertion that the

polymer is bound to a substrate material does not preclude the Ward reference from reading on their claims.

Claims 60,64-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batich et al. (US 2002/0177828) in view of Schoenfeldt et al. (US 2002/0172708) and in further view of Voorhees et al. (US 2004/0235950 A1), for the reasons set forth in the previous office action filed 03/06/2008.

Applicant's arguments filed 06/03/2008 have been fully considered but they are not persuasive. Applicants assert as previously argued that Batich does not teach an MMP active ingredient that is ionically associated with a quaternary ammonium polymer. Applicants assert that Schoenfeldt does not suggest a process where quaternary ammonium polymers or copolymers are components of polyionic polymers. Applicants also assert that Schoenfeldt does not suggest a process where the sol gel is bound to a substrate. Applicant's further state that Schoenfeldt does not teach a cationic polymer backbone comprised of quaternary ammonium groups and teaches away from ammonium copolymers because the reference recites the best results are achieved with primary amines. Applicants lastly assert that Voorhees does not suggest binding their compositions in conjunction with an insoluble substrate.

The examiner respectfully disagrees with the above assertions by applicants. The examiner noted in the last office action that Batich does not disclose ionic association of active drugs with the ammonium polymer, which is why it was combined with the Schoenfeldt reference. If Batich did disclose anionic MMP's in association with

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the cationic polymer the reference would be an anticipatory reference on its own merit, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As detailed in the previous office action Ward was used as a secondary reference for its disclosure on ionic association of MMP and cationic polymers. Since Ward and Voorhees are used as secondary references they do not have to disclose all of applicants claimed limitations on their own merit. Regarding applicants assertion that Voorhees does not describe a cationic polymer backbone comprised of quaternary ammonium groups, this limitation is simply not present in applicants claims, thus the examiner sees no reason to address the argument. Furthermore Schoenfeldt clearly recites that the polyionic polymer contains at least one cationic group which includes amines, a cationic amine is an ammonium ion (which includes protonated substituted amines). Disclosing cationic amines hardly teaches away from ammonium ions since they are in fact the same functional group.

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not


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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Application Number 	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/786,959	TOREKI ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	